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510(k) Summary – VPAP Adapt k 113801

Date Prepared	20th Dec, 2011
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Official Contact	Mr David D'Cruz – V.P., US Medical & Regulatory Affairs ResMed Corp. 9001 Spectrum Center Boulevard, San Diego, CA 92123 Tel: (858) 836-5984
Classification Reference	21 CFR 868.5905
Product Code	73 BZD
Common/Usual Name	Non continuous ventilator (IPPB).
Proprietary Name	VPAP Adapt
Predicate Device(s)	S9 VPAP Adapt (K102586)
Reason for submission	New Device

Indication for Use

The VPAP Adapt is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use.

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate devices.

- Same intended use
- Same operating principle
- Similar technologies
- Same manufacturing process

Design and Verification activities were performed on the VPAP Adapt System as a result of the risk analysis and design requirements. All tests (predicate bench testing) confirmed the product met the predetermined acceptance criteria. ResMed has determined that the new device has not altered the safety and effectiveness of CPAP/Bilevel treatment for patients with Obstructive Sleep Apnoea (OSA), central and/or mixed apneas, or periodic breathing who weigh more than 66 lb (>30 kg). The new device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Reviewer Guidance for Premarket Notification Submissions (November 1993)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)

Standards Testing:

The VPAP Adapt has been tested to appropriate FDA consensus standards and other applicable requirements passing all test protocols. The VPAP Adapt with and without the integrated heated humidifier (H5i) was designed and tested according to:

- IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for safety Medical electrical equipment – General requirements for basic safety and essential performance

Non-Clinical Testing

Predicate bench testing was used to show substantial equivalence between the S9 VPAP Adapt (K102586), and the VPAP Adapt.

ResMed conducted extensive bench testing using both closed-loop and open-loop test scripts from patient models designed to verify that the ASVAuto algorithm in the VPAP Adapt performs to specification. These tests included Adaptive servo-ventilation tests for the ASV functionality, and EPAP response tests to Flow Limitation, Snore and Apnea events for the auto-adjusting EPAP component. The bench test results demonstrated that the VPAP Adapt met the predetermined pass/fail criteria.

Device Description

VPAP Adapt System (VPAP Adapt *with* H5i) is similar to the predicate device(s), using a blower based positive pressure system with an integrated heated humidifier and heater controller. The device platform is identical to the S9 VPAP Adapt (K102586) and contains a Micro-processor controlled blower system that generates controlled positive airway pressure between 3-25 cmH_2O as required to maintain an "air splint" for effective treatment of OSA. The system comprises the flow generator, patient tubing, mask (patient interface) and humidifier.

The VPAP Adapt is a flow generator device designed to provide adaptive servo-ventilation therapy (ASV) to stabilize a patient's ventilation during sleep. The device continually measures the patient's instantaneous ventilation, and calculates a target ventilation based on to the patient's recent average. It then adjusts the degree of pressure support to servo-control the patient's ventilation to at least equal the target ventilation.

Therapy modes contained in the VPAP Adapt are CPAP, ASV, and ASVAuto. CPAP and ASV therapy modes come from the S9 VPAP Adapt (K102586).

The functional characteristics of the VPAP Adapt system includes all the clinician and user friendly features of the predicate device.

Conclusion

The VPAP Adapt is substantially equivalent to the Predicate device, S9 VPAP Adapt (K102586)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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MAY 25 2012

Re: K113801
Trade/Device Name: VPAP ADAPT
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: May 22, 2012
Received: May 24, 2012

Dear Mr. D'Cruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: VPAP Adapt

Indication for Use

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Prescription Use ___X___ AND/OR Over-The-Counter Use___

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113801